

US EPA ARCHIVE DOCUMENT

IV. Regulatory Position

A. 2003 Event MON863 Cry3Bb1 Corn Regulatory Position

Pursuant to FIFRA section 3(c)(7)(C), EPA may conditionally register a new pesticide active ingredient for a period of time reasonably sufficient for the generation and submission of required data that are lacking because insufficient time has elapsed since the imposition of the data requirement for those data to be developed. EPA may grant such conditional registration only if EPA determines that (1) the use of the pesticide product during the period of the conditional registration will not cause any unreasonable adverse effect on the environment, and (2) the registration and use of the pesticide during the conditional registration is in the public interest. EPA determines that all of these criteria have been fulfilled.

The first criterion under FIFRA section 3(c)(7)(C) mentioned above has been met since insufficient time has elapsed since the imposition of the data requirements for:

- 1) Independent laboratory analytical method validation.
- 2) Cry3Bb1 protein expression data in terms of dry weight, as the amount of protein present in the given tissue.
- 3) Field degradation studies evaluating accumulation and persistence of Cry3Bb1 protein in several different soils in various strata
- 4) Laboratory toxicity test with *Orius insidiosus* (minute pirate bug).
- 5) Laboratory toxicity test with carabid (ground beetle).
- 6) Laboratory toxicity test with *Tetraopes* (red milkweed beetle).
- 7) Intermediate and multi-year non-target organism field studies with statistical power.
- 8) A six week broiler dietary study.
- 9) Research regarding corn rootworm adult and larval movement and dispersal, mating habits, ovipositional patterns, number of times a female can mate and fecundity.
- 10) Research to determine if IRM strategies designed for WCRW and NCRW are appropriate for MCRW.
- 11) Research regarding the mechanism of potential resistance of CRW to MON 863. Monsanto must attempt to develop resistant CRW colonies to aid in determining selection intensity.
- 12) Research regarding the effect of WCRW ovipositing in soybean prior to overwintering and extended diapause in NCRW on an IRM strategy.
- 13) Detailed summaries of the four data-sets identified in Monsanto's December 13, 2002 letter should be submitted to the Agency to support their conclusion that the initial resistance allele frequency is ≤ 0.01 .
- 14) Continuation of baseline susceptibility studies currently underway for WCRW and initiation for NCRW and monitoring techniques such as discriminating dose concentration assays, as well as investigation of their feasibility as resistance monitoring tools.

As discussed above, the registration applicant has submitted or cited data sufficient for EPA to determine that a conditional registration under FIFRA 3(c)(7)(C) for the period ending May 1, 2004, will not result in unreasonable adverse effects on the environment. The human health effects data and non-target organism effects data are considered sufficient for the period of the conditional registration. These data demonstrate that no foreseeable human health hazards or ecological effects are likely to arise from the use of the product and that the risk of resistance developing to *Bacillus thuringiensis* Cry3Bb1 protein during the conditional registration is not expected to be significant. The data also demonstrate that there is virtually no possibility of any risk associated with weediness or outcrossing to wild relatives.

Registration of *Bacillus thuringiensis* Cry3Bb1 protein and the genetic material necessary for its production (vector ZMIR3L) in event MON863 corn is in the public interest because MON 863 corn is less risky to human health and/or the environment than currently registered pesticides and the improved season long protection and practical benefits of ease of MON 863 use exceed those of the currently registered alternatives, most of which are restricted use products. –Specifically:

- 1) for the first 3 year, MON 863 is projected to reduce conventional pesticide use by 12.5 million lbs active ingredient on 7.5 million corn acres (0.1 carbamates, 3.5 pyrethroids, 3.0 organophosphates, and 0.9 for other chemical classes. This totals to 7.5 million acres of use reduction. To the extent that MON 863 is used on acreage that would be uneconomical to otherwise treat, the total use reduction would be less than the MON 863 acres adoption.)
- 2) it has a predicted yield benefit of 1.5 – 4.5% per acre greater than conventionally treated corn,
- 3) grower benefits are estimated at \$6.56 per acre vs. conventionally treated corn,
- 4) the total first 3 year economic benefits are estimated at \$49.2 million.

(EPA's public interest analysis considers three years of MON 863 use, because EPA has been informed that Monsanto will request that the current tolerance exemption for Cry 3bB1, which expires on May 1, 2004, be amended to remove the expiration date. If (1) Monsanto requests such an amendment to the Cry 3Bb1 tolerance exemption, (2) EPA grants such amendment request, and (3) Monsanto subsequently requests that the MON 863 registration be amended to expire at a later date, EPA currently believes that the data reviewed so far likely will support an extension of the conditional registration for an additional two years.)

In view of these minimal risks and the clear benefits related to YieldGard Rootworm, EPA believes that the use of the product during the limited period of the conditional registration will not cause any unreasonable adverse effects.

Although the data with respect to this particular new active ingredient are satisfactory, it is not sufficient to support an unconditional registration under FIFRA 3(c)(5). Additional data are

necessary to evaluate the risk posed by the continued use of this product. Consequently, EPA is imposing the data requirements specified earlier in the Biopesticide Registration Action Document in Section III.

EPA has determined, as explained in the attached BRAD section II.E., that the third criterion for a FIFRA 3(c)(7)(C) conditional registration has been fulfilled because the use of Cry3Bb1 corn under this registration would be in the public interest.

A tolerance exemption has been granted pursuant to FFDCA section 408(d) for *Bacillus thuringiensis* Cry3Bb1 protein and the genetic material necessary for its production in corn. However, this tolerance exemption expires in May 2004 and therefore, this registration would also expire in May 2004 until such time as the tolerance exemption is amended to extend its duration. If the tolerance exemption is amended to extend its duration, EPA believes that current data and information reviewed would support an amendment of the conditional registration to expire in three years from the date of the original registration.

Conclusion

The submitted data in support of this registration under section 3(c)(7)(C) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) have been reviewed and determined to be adequate. Studies mentioned above are included in the terms, conditions, and limitations of this registration. EPA determines that, for the period of conditional registration, this registration will not cause unreasonable adverse effects to man or the environment and is in the public interest.

Based on the data submitted and cited by the applicants and reviewed by Biopesticides and Pollution Prevention Division, EPA has concluded that the Monsanto Company Cry3Bb1 corn product containing the new active ingredient *Bacillus thuringiensis* Cry3Bb1 Protein and the Genetic Material Necessary for its Production (Vector ZMIR13L) in Event MON863 Corn be REGISTERED under FIFRA section 3(c)(7)(C), with appropriate limitations.

B. 2005 MON 88017 & MON 88017 x MON 810 Regulatory Position

Pursuant to FIFRA section 3(c)(7)(C), EPA may conditionally register a new pesticide active ingredient for a period of time reasonably sufficient for the generation and submission of required data that are lacking because insufficient time has elapsed since the imposition of the data requirement for those data to be developed. EPA may grant such conditional registration only if EPA determines that (1) the use of the pesticide product during the period of the conditional registration will not cause any unreasonable adverse effect on the environment, and (2) the registration and use of the pesticide during the conditional registration is in the public interest. BPPD determines that all of the relevant criteria have been fulfilled.

BPPD determined that it is appropriate to conditionally register the MON 88017 products under

Section 3(c)(7)(C) for a period of time (specified below) reasonably sufficient for the generation and submission of certain data that are lacking because insufficient time has elapsed since the imposition of those data requirements. Specifically,

- 1) For MON 88017, all data that was previously required as a condition of registration to support the individual plant-incorporated protectant in Event MON863 (YieldGard Rootworm), 524-528, are necessary. In the event that the Agency concludes that the MON 863 (YieldGard Rootworm) studies required in connection with the MON 863 conditional registration do not sufficiently demonstrate a lack of significant adverse effects, additional data with MON 88017 corn must be submitted. This data may include a) laboratory toxicity testing with *Orius insidiosus* (minute pirate bug), b) laboratory toxicity testing with a carabid (ground beetle), c) long range effects testing on invertebrate populations in the field, and d) long range soil persistence testing.
- 2) For MON 88017 x MON 810, all data required to support the individual plant-incorporated protectants in MON 810 (YieldGard), Event MON863 (YieldGard Rootworm), MON 88017 corn; EPA Registration Nos. 524-489, 524-528, are necessary. In the event that the Agency concludes MON 863 (YieldGard Rootworm) studies do not sufficiently demonstrate a lack of significant adverse effects, additional data with MON 88017 x MON 810 corn must be submitted. This data may include a) laboratory toxicity testing with *Orius insidiosus* (minute pirate bug), b) laboratory toxicity testing with a carabid (ground beetle), c) long range effects testing on invertebrate populations in the field, and d) long range soil persistence testing. Additionally, expression level data regarding Cry1Ab protein levels in MON 810 and MON 88017 x MON 810 young root and forage root are required within 12 months of the date of registration.

At this time, the applicant has submitted or cited data sufficient for BPPD to determine that conditional registration of *Bacillus thuringiensis* Cry3Bb1 protein and the genetic material necessary for its production (Vector ZMIR39) in MON 88017 corn (OECD Unique Identifier: MON-88017-3) corn under FIFRA 3(c)(7)(C) will not result in unreasonable adverse effects to the environment during the period of conditional registration, as discussed above. Monsanto submitted and/or cited satisfactory data pertaining to the proposed use. The human health effects data and non-target organism effects data are considered sufficient for the period of the conditional registration. These data demonstrate that no foreseeable human health hazards or ecological effects are likely to arise from the use of the products during the period of conditional registration and that the risk of resistance developing to Cry3Bb1 proteins during the conditional registrations are not expected to be significant.

Registration of MON 88017 and MON 88017 x MON 810 is in the public interest due to the following.

- Replacement of higher risk pesticides;

- ▶ Practical benefits for growers (reduced input costs, time and labor savings, etc.);
- ▶ Efficacy (equivalent to conventional insecticides);
- ▶ Human health benefits (reduced toxicity relative to conventional insecticides);
- ▶ Environmental benefits (reduced risks to non-target organisms relative to conventional insecticides);
- ▶ Yield benefits (greater yields than conventional corn);
- ▶ Grower economic benefits (total benefits up to \$6.56 per acre);
- ▶ Herbicide tolerance: MON 88017 (and MON 88017 x MON 810) have been engineered to tolerate glyphosate herbicide applications. This trait will provide economic benefits to growers.
- ▶ Enhanced breeding efficiency: MON 88017 can be bred faster (and selected through the herbicide tolerance trait) which should allow for a greater supply of the product to growers.

In view of these minimal risks and the clear benefits related to MON 88017 (in both the MON 88017 and MON 88017 x MON 810 products), BPPD believes that the use of the products during the limited period of the conditional registration will not cause any unreasonable adverse effects.

Although the data with respect to this particular new active ingredient are satisfactory, they are not sufficient to support an unconditional registration under FIFRA 3(c)(5). As noted above, additional data are necessary to evaluate the risk posed by the continued use of this product. Consequently, the Agency has imposed the data requirements specified earlier in the attached Biopesticide Registration Action Document in Section III.

Permanent tolerance exemptions exist and are applicable to the MON 88017 products, MON 88017 and MON 88017 x MON 810.

Based on the data submitted and cited by the applicants and reviewed by EPA, the EPA registered the Monsanto Cry3Bb1 MON 88017 corn products containing the new active ingredient *Bacillus thuringiensis* Cry3Bb1 protein and the genetic material necessary for its production (Vector ZMIR39) in MON 88017 corn (OECD Unique Identifier: MON-88Ø17-3) be REGISTERED under FIFRA section 3(c)(7)(C), with appropriate limitations.

The expiration data of the registration has been set to September 30, 2010 for MON 88017 and October 15, 2008 for MON 88017 x MON 810 (due to the MON 810 2008 expiration date.)